## *REMARKS*

Claims 11, 13-14, 18-20, 33-41, 44, 50-55, 57-58, and 60-62 are pending in the present application. Claims 12, 15, 42-43, 56, and 59 have been canceled without prejudice or disclaimer. Claim 11 and 18 have been amended to recite that "the acid-labile active compound is selected from the group consisting of an substituted pyridin-2-yl-methylsulfinyl-1H-benzimidazoles, substituted phenylmethylsulfinyl-1H-benzimidazoles, substituted cycloheptapyridin-9-ylsulfinyl-1H-benzimidazoles, and substituted pyridin-2-ylmethylsulfinylthienoimidazoles and may be present as a chiral compound, a pure enantiomer, or a mixture thereof in any mixing ratio, or in the form of its salt with a base, or in the form of a hydrate of its salt with a base." Additionally, claim 18 has been amended to correct a typographical error. Claims 33-36 have been amended in accordance with the amendment to claims 11 and 18. New claims 61 and 62 are directed to the oral solid active compound unit of claims 11 and 18 respectively, the wherein the at least one fatty alcohol is a linear, saturated or unsaturated primary alcohol having 10-30 carbon atoms.

No new matter has been added within the meaning of 35 USC § 132.

In view of the following, further and favorable consideration is respectfully requested.

### 1. Rejection of claims 11 and 18 under 35 U.S.C. §112

The Official Action states that claims 11 and 18 are rejected under 35 U.S.C. § 112 reciting new matter.

In particular, the Official Action states the following:

> Applicant's recitation of "wherein the microsphere does not comprise an enteric coating" in instant claims 11 & 18 presents new matter since there is lack of support for this limitation in the present specification. While the limitation "the acid-labile active compound does not have to be protected by an enteric coating" is supported by the instant disclosure at page 3, first paragraph, the limitation "wherein the microsphere does not comprise an enteric coating" is not supported by the instant specification. Examiner requests clarification as to where in the instant specification support for the new limitation can be found.

## RESPONSE

Applicants respectfully traverse this rejection of presently pending claims 11 and 18 under 35 U.S.C. § 112.

Applicants respectfully submit that the present limitation that "the microsphere does not comprise an enteric coating," as recited present claims 11 and 18, is not new matter within the meaning of 35 USC § 112. Specifically, Applicants submit the skilled artisan would understand the teaching of the specification as including the limitation that the microsphere does not comprise an enteric coating.

Applicants respectfully reiterate that the present specification provides sufficient disclosure for the phrase "the microsphere does not comprise an enteric coating." For example, as described in the paragraph bridging pages 10 and 11 of the present specification, the specification provides support for a dosage form, i.e., an oral solid active compound unit, that is not enteric coated. In this regard, the first sentence of the paragraph bridging pages 10 and 11 discloses that ***"[t]he individual active compound units (preparations) according to the invention can then be used as the basis for the production of the administration forms***

***according to the invention."*** The paragraph goes on to enumerate several acceptable administration or dosage forms. The paragraph ends with the sentence, "[i]n the case of peroral administration forms, it is surprisingly possible to dispense with the enteric coating." Accordingly, reading the paragraph in its entirety, a skilled artisan would take the teaching of the last sentence as meaning that in the case of oral administration the individual active compound unit does not need to be enteric coated. Accordingly, ***it would follow that as the oral solid active compound unit does not comprise an enteric coating, a component of the oral solid active compound unit, i.e., the microsphere, does not comprise an enteric coating.*** In other words, as an integral structure of the individual active compound, the microsphere would also be precluded from containing an enteric coating.

Additionally, applicants respectfully note that in one embodiment, the present specification describes the active compound units as microspheres. Specifically, as described at page 4, paragraph 3, of the present specification:

> The multiple individual active compound units (also described in preparations below) within the meaning of the invention are multiple individual units, in which at least one active compound particle is present in a matrix made of a mixture comprising at least one fatty alcohol and at least one solid paraffin.... ***Preferably the active compound units are microspheres***.

Again, as the acid-labile active compound unit does not have to be enteric coated, it would follow that the microsphere does not have to be enteric coated. Applicants respectfully submit that upon a cursory reading of the specification a skilled artisan would realize, and understand, that the microsphere does not comprise an enteric coating.

Therefore, applicants submit that the limitation the present limitation that "the

microsphere does not comprise an enteric coating," as recited claims 11 and 18, is not new matter within the meaning of 35 USC § 112. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 11 and 18.

**2. Rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58, and 60 under 35 USC § 112, first paragraph.**

The Official Action states that claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58, and 60 are rejected under 35 U.S.C. § 112, first paragraph, as not being enabled.

In particular, the Official Action states the following:

(1). Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific fatty alcohols disclosed on page 5 of the specification, does not reasonably provide enablement for the generic "fatty alcohol". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the specific fatty alcohols disclosed on page 5, ¶ 5 of the specification. Namely, Applicants are only enabled for a fatty alcohol that is a linear, saturated or unsaturated primary alcohol having 10-30 carbon atoms. Applicants are non-enabled for all fatty alcohols. The definition of fatty alcohols as presented in the specification (page 5, 5) should be incorporated into all generic claims.

(2). Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the acid-labile compounds being substituted benzimidazoles disclosed on page 4 of the specification, does not reasonably provide enablement for the generic "acid labile active compounds". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the benzimidazoles listed on page 4, ¶ 7 of the specification. The generic recitation of "acid labile active compounds" recited in the instant claims renders the claims non-enabling. Applicant has only identified the "substituted benzimidazoles" to be useful for their invention. Thus,

Applicant's claims should be amended to reflect the particular benzimidazoles as recited on page 4 of the specification.

(3). Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the examples at pages 14-17, which require the inclusion of a stearylamine and a polymer in addition to the fatty alcohol, does not reasonably provide enablement for the generic "fatty alcohol" without inclusion of the stearylamine and polymer. The specification examples demonstrate that the stearylamine and polymer (i.e., povidone) are required to form the active compound units. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the combination of a fatty alcohol, stearylamine and polymer. The examples demonstrate that the excipients refer to the stearylamine and polymer. The claims must include the presence of stearylamine and polymer, in addition to the fatty alcohol claimed, as this would be enabling. Applicant's claims should be amended to reflect incorporation of all three components of a fatty alcohol, stearylamine and polymer in order to render the claims enabling.

## RESPONSE

Applicants respectfully traverse each of the rejections of presently pending claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58, and 60 under 35 U.S.C. § 112, first paragraph.

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, first paragraph (2000). The purpose of this requirement is to ensure that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v.*

*Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); *see also* Donald S. Chisum, 3 *Chisum on Patents* § 7.01 (2002).

Accordingly, the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not experimentation.'" *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Routine experimentation does not constitute undue experimentation. *See Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. *See, e.g., Nat'l Recovery Techs.*, 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); *In re Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright,* 999 F.2d 1557 (Fed. Cir. 1993).

Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact. *CFMT*, 349 F.3d at 1337. Furthermore, "[w]hether undue experimentation is needed is not a single, simple factual

determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d at 737.

Some of these considerations, commonly referred to as "the *Wands* factors," include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.; see also Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating that the *Wands* factors "are illustrative, not mandatory" and that what is relevant to an enablement determination depends upon the facts of the particular case).

In the present case, Applicant asserts that the specification, figures, and examples, provide ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the presently pending claims without undue experimentation.

With regard specific regard to the Examiner's assertions in (1) and (2) above, i.e., that the specification does not reasonably provide enablement for the generic phrase "fatty alcohol" and that the specification does not provide enablement for the generic phrase "acid labile active compounds," applicants politely remind the Examiner that the scope of the claims is not limited to the specific embodiments disclosed in the specification. Again, as held in *In re Wright, "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." See In re Wright.*

With specific regard to the phrase fatty alcohol, Applicants note that the several examples set forth in the present specification at page 5, paragraph 5 are more than sufficient to satisfy the enablement requirement of 35 USC § 112, first paragraph. With specific regard to the phrase "acid labile active compounds," Applicants note that the several examples set forth on pages 4 and 5 of the present specification are more than sufficient to satisfy the enablement requirement of 35 USC § 112, first paragraph. Accordingly, applicants submit that a skilled artisan would be able to fully make and use the claimed subject matter in view of both the disclosure of the specification and that which is commonly known in the art.

With further reference to the Examiner's assertion set forth in (2) above, applicants note that solely in order to expedite prosecution, claims 11 and 18 have been amended to recite that the acid-labile active compound is "substituted pyridin-2-yl-methylsulfinyl-1H-benzimidazoles, substituted phenylmethylsulfinyl-1H-benzimidazoles, substituted cycloheptapyridin-9-ylsulfinyl-1H-benzimidazoles, and substituted pyridin-2-ylmethylsulfinylthienoimidazoles and may be present as a chiral compound, a pure enantiomer, or a mixture thereof in any mixing ratio, or in the form of its salt with a base, or in the form of a hydrate of its salt with a base."

With regard to the Examiner's assertion set forth in (3) above, applicants respectfully submit that ***Examples 11-13, at page 15, of the specification clearly disclose preparations having only solid paraffin and fatty alcohol***. Contrary to the Examiner's assertion, Examples 11-13 do not require the inclusion of a stearylamine or a polymer. Accordingly, applicants submit that the present specification provides sufficient enablement for a "fatty alcohol" without inclusion of

a stearylamine and polymer.

Therefore, applicants respectfully submit that the presently pending subject matter is fully compliant with 35 USC § 112, first paragraph. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

## Conclusion

In view of the foregoing, applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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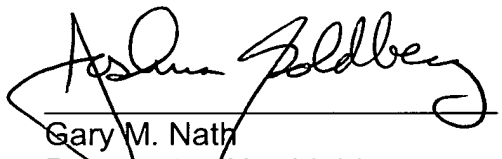

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